I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450. Alexandria, VA 22313-1450

INFORMATION DISCLOSURE

STATEMENT

Examining Group 1645

Patent Application

Docket No. USF-200TCXZ1

Serial No. 10/567,298

April

adwig, Patent Attorney

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APR 0 6 2007

(Not yet assigned)

1645

Applicants

M. Ian Phillips, Yao Liang Tang

Serial No.

10/567,298

Filed

February 6, 2006

For

Vigilant Cells

MS AMENDMENT

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§1.97 AND 1.98

Sir:

In accordance with 37 C.F.R. §1.56, the references listed on the attached form PTO/SB/08 are being brought to the attention of the examiner for consideration in connection with the examination of the above-identified patent application. A copy of each cited reference is enclosed.

The applicants respectfully assert that the substantive provisions of 37 C.F.R. §§1.97 and 1.98 are met by the foregoing statement.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Respectfully submitted

Glenn P. Ladwig Patent Attorney

Registration No. 46,853

Phone No.:

352-375-8100 352-372-5800

Fax No.:

Address: P.O. Box 142950

Gainesville, FL 32614-2950

GPL/mv

Attachments: Form PTO/SB/08 (5 pages); copies of references cited therein

J:\USF\200TCXZI\PTO\IDS.pto.doo/DNB/mv

APR 0 6 2007

PTO/SB/08A (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paper Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known Substitute for form 1449A/PTO **Application Number** 10/567,298 INFORMATION DISCLOSURE **Filing Date** February 6, 2006 STATEMENT BY APPLICANT **First Named Inventor** M. Ian Phillips (use as many sheets as necessary) **Art Unit** 1645 **Examiner Name** of **Attorney Docket Number** Sheet 1 5 USF-200TCXZ1

U.S. PATENT DOCUMENTS							
Examiner Initials*	Cite No. 1	Document Number Number - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
	U1	US-10/567,275	02-06-2006	Phillips et al. (patent application)	All		
	٦	US-					
	٦	US-					
	כ	US-					
	٦	US-					
-	Ü	US-					
	U	US-					
	υ	US-					
	U	US-					

	FOREIGN PATENT DOCUMENTS							
		Foreign Patent Document	Publication Date	Name of Patentee or	Pages, Columns, Lines,			
Examiner	Cite		MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear			
tnitials*	No. 1	Country Code 3 - Number 4 - Kind Code5 (if known)			o, resorant igains , press	T ⁶		
5. 0. 10.	F1	WO 2005/017165 A1	02-24-2005	Univ. of South Florida	All			
	F2	WO 2004/024867 A2	03-25-2004	Univ. of Florida	All			
	F3	WO 00/50048 A3	08-31-2000	Univ. of Pittsburgh	All			
	F							
	F							
	F							
	F							

	 	
Examiner	l Date	
Signature	Considered	
(Olymature	 00.10.00	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard T.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

				Complete if Known		
	e for form 1449B/PT		OCUPE	Application Number	10/567,298	
	RMATION [Filing Date	February 6, 2006	
STATEMENT BY APPLICANT				First Named Inventor	M. Ian Phillips	
4			eeeeed)	Group Art Unit	1645	
(u.	se as many sheets	s as nec	essary)	Examiner Name		
Sheet	2	of	5	Attorney Docket Number	USF-200TCXZ1	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	R1	ABRUZZESE, R. et al. "Ligand-dependent regulation of vascular endothelial growth factor and erythropoietin expression by a plasmid-based autoinducible GeneSwitch system" Mol. Therapy, 2000, 2:276-287.	
	R2	CHEN, H. et al. "Protection against ischemia-reperfusion injury and myocardial dysfunction by antisense- oligodeoxynucleotide by antisense-oligodeoxynucleotide directed at angiotensin-converting enzyme mRNA" Gene Ther., 2001, 8:804-810.	
	R3	CHEN, H. et al. "Protection against myocardial dysfunction induced by global ischemia-reperfusion by antisense- oligodeoxynucleotides directed by β₁-adrenoceptor mRNA" J. Pharmacol. Exp. Ther., 2000, 294:722-727.	
	R4	CONGET, P.A. and MINGUELL, J.J. "Adenoviral-mediated gene transfer into ex vivo expanded human bone marrow mesenchymal progenitor cells" <i>Exp. Hematol.</i> , 2000, 28:382-390.	
	R5	DAVANI, S. et al. "Mesenchymal progenitor cells differentiate into an endothelial phenotype, enhance vascular density, and improve heart function in a rat cellular cardiomyoplasty model" <i>Circulation</i> , 2003, 108(Suppl. 1):	
	R6	FRANZ, W.M. et al. "Heart-specific targeting of firefly luciferase by the myosin light chain-2 promoter and developmental regulation in transgenic mice" Circ. Res., 1993, 73:629-638.	
	R7	GINIGER, E. et al. "Specific DNA binding of GAL4, a positive regulatory protein of yeast" Cell, 1985, 40:767-774.	
	R8	GU, J. et al. "Tumor-specific transgene expression from the human telomerase reverse transcriptase promoter enables targeting of the therapeutic effects of the Bax gene to cancers" Cancer Res., 2000, 60:5359-5364.	
	R9	HABERMAN, R. et al. "Inducible long-term gene expression in brain with adeno-associated virus gene transfer" Gene Therapy, 1998, 5:1604-1611.	
	R10	HALABY, I. et al. "Glucocorticoid-regulated VEGF expression in ischemic skeletal muscle" Mol. Therapy, 2002, 5:300-306.	
	R11	HUANG, L.E. et al. "Regulation of hypoxia-inducible factor 1α is mediated by an O ₂ -dependent degradation domain via the ubiquitin-proteasome pathway" <i>Proc Natl Acad Sci USA</i> , 1998, 95:7987-7992.	
	R12	KAGIYAMA, T. et al. "Expression of angiotensin type 1 and 2 receptors in brain after transient middle cerebral artery occlusion in rats" Regul. Pept., 2003, 110:241-247.	
	R13	KEEGAN, L. et al. "Separation of DNA binding from the transcription-activating function of a eukaryotic regulatory protein" Science, 1986, 231:699-704.	

Examiner	Date
Signature	Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

^{*}EXAMINER: Initial it reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Approved for use through 07/31/2006, OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

				Complete if Known		
	stitute for form 1449B/P		OCUDE	Application Number	10/567,298	
	FORMATION			Filing Date	February 6, 2006	
S ⁻	TATEMENT B'	Y APP	LICANT	First Named Inventor	M. lan Phillips	
	(vee on many about	to oo noo		Group Art Unit	1645	
	(use as many shee	is as nec	essary)	Examiner Name		
Sheet	3	of	5	Attorney Docket Number	USF-200TCXZ1	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	item thook manazine intimat senat symposium catalog etc.) date dabetst voit		T²
	R14	KIMURA, B. et al. "Attenuation of hypertension and heart hypertrophy by adeno-associated virus delivering angiotensinogen antisense" <i>Hypertension</i> , 2001, 37:376-380.	
-	R15	KIRCHEIS, R. et al. "Polyethylenimine/DNA complexes shielded by transferring target gene expression to tumors after systemic application" <i>Gene Ther.</i> , 2001, 8:28-40.	
	R16	KOH, G.Y. et al. "Targeted expression of transforming growth factor-β1 in intracardiac grafts promotes vascular endothelial cell DNA synthesis" <i>J. Clin. Invest.</i> , 1995, 95:114-121.	
	R17	KOLLET, O. et al. "HGF, SDF-1, and MMP-9 are involved in stress-induced human CD34* stem cell recruitment to the liver" J. Clin. Invest., 2003, 112:160-169.	
	R18	MANGI, A.A. et al. "Mesenchymal stem cells modified with Akt prevent remodeling and restore performance of infracted hearts" Nat. Med., 2003, 9:1195-1201.	
	R19	MELO, L. et al. "Gene therapy strategy for long-term myocardial protection using adeno-associated virus-mediated delivery of heme oxygenase gene" Circulation, 2002, 105:602-607.	
	R20	OGRIS, M. et al. "The size of DNA/transferring-PEI complexes is an important factor for gene expression in cultured cells" Gene Ther., 1998, 5:1425-1433.	
	R21	PHILLIPS, M.I. "Gene therapy for hypertension: Antisense inhibition with adeno-associated viral vector delivery targeting angiotensin II type 1 receptor messenger ribonucleic acid" Am. J. Cardiol., 1998, 82(10A):60S-62S.	
	R22	PHILLIPS, M.I. "Somatic gene therapy for hypertension" Braz. J. Med. Biol. Res., 2000, 33:715-721.	
	R23	PHILLIPS, M.I. "Is gene therapy for hypertension possible?" <i>Hypertension</i> , 1999, 33:8-13.	
· · · · · · · · · · · · · · · · · · ·	R24	PHILLIPS, M.I. "Gene therapy for hypertension: The preclinical data" <i>Hypertension</i> , 2001, 38(3 Pt 2):543-548.	
	R25	PHILLIPS, M.I. "Gene therapy for hypertension: sense and antisense strategies" <i>Expert. Opin. Biol. Ther.</i> , 2001, 1(4):655-662, abstract.	
	R26	PHILLIPS, M.I. et al. "Vigilant vector: Heart-specific promoter in an adeno-associated virus vector for cardioprotection" <i>Hypertension</i> , 2002, 39(2 Pt 2):651-655.	

Examiner	Date
Signature	Considered

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form. call 1-800-PTO-9199 (1-800-PTO-9199) and select option 2

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

				Con	Complete if Known		
	ite for form 1449B/PTO		SOUDE	Application Number	10/567,298		
	RMATION D			Filing Date	February 6, 2006		
STA	TEMENT BY	APPL	ICANT.	First Named Inventor	M. Ian Phillips		
				Group Art Unit	1645		
(1	use as many sheets	as neces	isary)	Examiner Name			
Sheet	4	of	5	Attorney Docket Number	USF-200TCXZ1		

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	R27	PHILLIPS, M.I. "Gene therapy for hypertension: The preclinical data" <i>Methods Enzymol.</i> , 2002, 346:3-13.	
	R28	PONNAZHAGAN, S. et al. "Adeno-associated virus type 2-mediated transduction of murine hematopoietic cells with long-term repopulating ability and sustained expression of a human globin gene in vivo" J. Virology, 1997, 71:3098-3104.	
	R29	QIAO, J. et al. "Tumor-specific transcriptional targeting of suicide gene therapy" Gene Therapy, 2002, 9:168-175.	
	R30	RUAN, H. et al. "A hypoxia-regulated adeno-associated virus vector for cancer-specific gene therapy" Neoplasia, 2001, 3:255-263.	
	R31	SCHMITZ, M.L. and BAEUERLE, P.A. "The p65 subunit is responsible for the strong transcription activating potential of NF-kB" <i>EMBO J.</i> , 1991, 10:3805-3817.	
	R32	SEMENZA, G.L. et al. "Hypoxia response elements in the aldolase A, enolase 1, and lactate dehydrogenase A gene promoters contain essential binding sites for hypoxia-inducible factor 1" <i>J Biol Chem.</i> , 1996, 271:32529-32537.	
	R33	SHAKE, J.G. et al. "Mesenchymal stem cell implantation in a swine myocardial infarct model: engraftment and functional effects" Ann. Thorac. Surg., 2002, 73:1919-1926.	
	R34	SIRTORI, C.R. "New targets for lipid lowering and atherosclerosis prevention" <i>Pharmacol. Ther.</i> , 1995, 67:433-447.	
	R35	SMITH-ARICA, J.R. et al. "Switching on and off transgene expression within lactotrophic cells in the anterior pituitary gland in vivo" Endocrinology, 2001, 142:2521-2532.	
	R36	STRAUER, B.E. and KORNOWSKI, R. "Stem cell therapy in perspective" Circulation, 2003, 107:929-934.	
	R37	TANG, X. et al. "Intravenous angiotensinogen antisense in AAV-based vector decreases hypertension" Am. J. Physiol., 1999, 277(6 Pt 2):H2392-H2399.	
	R38	TANG, Y.L. et al. "Paracrine action enhances the effects of autologous mesenchymal stem cell transplantation on vascular regeneration in rat model of myocardial infarction" Ann Thorac. Surg., 2005, 80:229-237.	
	R39	TANG, Y.L. et al. "A hypoxia-inducible vigilant vector system for activating therapeutic genes in ischemia" Gene Ther., 2005, 12:1163-1170.	

Examiner	Date
Signature	Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional).

Applicant is unique citation designation number (optional).

Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

				Complete if Known		
Substitute for form 1449B/PTO				Application Number	10/567,298	
INFORMATION DISCLOSURE				Filing Date	February 6, 2006	
STATEMENT BY APPLICANT (use as many sheets as necessary)				First Named Inventor	M. Ian Phillips	
				Group Art Unit	1645	
				Examiner Name		
Sheet	5	of	5	Attorney Docket Number	USF-200TCXZ1	

NON PATENT LITERATURE DOCUMENTS							
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²				
	R40	TANG, Y. et al. "Hypoxia inducible double plasmid system for myocardial ischemia gene therapy" Hypertension, 2002, 39(2 Pt 2):695-698.					
	R41	TANG, Y.L. et al. "Protection from ischemic heart injury by a vigilant heme oxygenase-1 plasmid system" Hypertension, 2004, 43:746-751.					
	R42	TANG, Y.L. et al. "Improved graft mesenchymal stem cell survival in ischemic heart with a hypoxia-regulated heme oxygenase-1 vector" J. Am. Coll. Cardiol., 2005, 46:1339-1350.					
	R43	TANG, Y.L. et al. "A vigilant, hypoxia-regulated heme oxygenase-1 gene vector in the heart limits cardiac injury after ischemia-reperfusion in vivo" J. Cardiovasc. Pharmacol. Ther., 2005, 10:251-263.					
	R44	TANG, Y. et al. "Vigilant vectors: adeno-associated virus with a biosensor to switch on amplified therapeutic genes in specific tissues in life-threatening disease" Methods, 2002, 28:259-266.					
	R45	TANG, Y.L. et al. "Autologous mesenchymal stem cell transplantation induce VEGF and neovascularization in ischemic myocardium" Regul. Pept., 2004, 117:3-10.					
	R46	TANG, Y.L. et al. "Mobilizing of haematopoietic stem cells to ischemic myocardium by plasmid mediated stromal-cell-derived factor-1α (SDF-1α) treatment" Regul. Pept., 2005, 125:1-8.					
	R47	WOO, Y.J. et al. "Recombinant adenovirus-mediated cardiac gene transfer of superoxide dismutase and catalase attenuates postischemic contractile dysfunction" Circulation, 1998, 98:II255-II261.					
	R48	WU, P. et al. "Adeno-associated virus vector-mediated transgene integration into neurons and other nondividing cell targets" J. Virol., 1998, 72:5919-5926.					
•	R49	YAMAGUCHI, J. et al. "Stromal cell-derived factor-1 effects on ex vivo expanded endothelial progenitor cell recruitment for ischemic neovascularization" Circulation, 2003, 107:1322-1328.					
	R50	YANG, B.C. et al. "Critical role of AT1 receptor expression after ischemia/reperfusion in isolated rat hearts: Beneficial effect of antisense oligodeoxynucleotides directed at AT1 receptor mRNA" Circ. Res., 1998, 83:552-559.					
	R51	YANG, B.C. et al. "Increase in angiotensin II type 1 receptor expression immediately after ischemia-reperfusion in isolated rat hearts" <i>Circulation</i> , 1997, 96:922-926.					
	R52	ZVARITCH, E. et al. "The transgenic expression of highly inhibitory monomeric forms of phospholamban in mouse heart impairs cardiac contractility" J. Biol. Chem., 2000, 275:14985-14991.					

Examiner	Date
Signature	Considered

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional).

Applicant is unique citation designation number (optional).

Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.